

PATENT APPLICATION

Attorney Docket: 2007-3569,ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App of	:	Rivron et al.	Art Group:	3738
Serial No.	:	10/656,855	Conf. No.:	8584
Filing Date	:	September 4, 2003	Date:	November 13, 2007
For	:	IMPLANTABLE MEDICAL DEVICES HAVING RECESSES		

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**REPLY BRIEF**

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Sir:

This Reply Brief is submitted in response to the Examiner's Answer of September 10, 2007 to Applicant's Appeal Brief filed on May 21, 2007.

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### **Real Party in Interest**

Pursuant to an Assignment dated October 9, 2007, the real party in interest is now Kips Bay Medical, Inc. of Minneapolis, Minnesota.

### **Related Appeals and Interferences**

There are no related appeals or interferences for the above-referenced patent application.

### **Status of Claims**

Claims 11, 12, 14-34, and 37-41 are pending and are subject of this appeal.

Claims 11, 12, 14-17, 19, 20, 22, and 33 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 4,596,577 to Sato (hereinafter “Sato ‘577”).

Claims 19, 23, 24-30, and 32-34 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 6,352,555 to Dzau et al. (hereinafter “Dzau et al. ‘555”).

Claims 18, 21, 31, 32, 34, and 37-41 stand rejected under 35 U.S.C. §103(a) as being unpatentable in view of Sato ‘577.

Certain of the claim rejections stated above are different than the claim rejections contained in the final Office Action dated December 22, 2006. Specifically, Claims 21, 31, 32, and 36-41 are no longer rejected under 35 U.S.C. §102(b) as being unpatentable over Sato ‘577. Moreover, Claims 35 and 36 are no longer rejected under 35 U.S.C. §102(b) as being unpatentable over Dzau et al. ‘555. However, Claim 32 now stands rejected under 35 U.S.C. §102(b) as being unpatentable over Dzau et al. ‘555.

Finally, Claim 21, 31, 32, 34, and 37-41 now stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sato ‘577 in accordance with the new ground of rejection applied in Examiner’s Answer dated September 10, 2007.

### **Status of Amendments**

The status of amendments described in Applicants’ Appeal Brief dated May 21, 2007 remains accurate.

### **Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in Applicants' Appeal Brief dated May 21, 2007 remains accurate.

### **Grounds of Rejection to be Reviewed on Appeal**

The Appellants submit the following grounds of rejection to be reviewed on appeal:

1. The rejection of Claims 11, 12, 14-17, 19, 20, 22, and 23 under 35 U.S.C. §102(b) as being unpatentable over Sato '577;
2. The rejection of Claims 19, 23, 24-30, and 32-34 under 35 U.S.C. §102(b) as being unpatentable over Dzau et al. '555; and
3. The rejection of Claims 18, 21, 31, 32, 34, and 37-41 under 35 U.S.C. §103(a) as being unpatentable in view of Sato '577.

### **Argument**

#### **Rejection of Claims under 35 USC §103(a) in view of Sato '577.**

The Examiner has entered a new ground of rejection in the Examiner's Answer dated September 10, 2007. Specifically, the new ground of rejection is that Claims 21, 31, 32, 34, and 37-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sato '577. The Sato '577 patent, however, fails to teach or suggest the elements of such claims as required by 35 U.S.C. §103(a). In particular, nowhere does Sato '577 teach or suggest the directionality of applied frictional force recited in the above-noted rejected claims. The Examiner acknowledges this lack of disclosure in Sato '577 at page 6 of the Examiner Answer, and instead asserts that such a requirement is "an obvious matter of design choice". The Examiner attempts to substantiate such an assertion by stating that the claimed rubbing direction does not provide any advantage, solves the stated problem, or is used for any particular purpose.

To the contrary, the directionality of force and position recited in each of the claims rejected under 35 U.S.C. §103(a) is specifically described in paragraphs 54 and 56 of the specification as being particularly effective in lifting nodes from the luminal surface to define a plurality of recesses. Paragraph 54, for example, specifically sets

forth that rubbing directions other than transverse<sup>1</sup> are not as efficient in lifting nodes from the luminal surface, which is a primary object of the present invention. Accordingly, the claimed directionality does in fact provide a specific advantage in lifting nodes from the luminal surface thereby defining a plurality of recesses.

The Examiner's assertion that the claimed directionality of imposition of frictional force is merely an obvious matter of design choice fails to find support in Sato '577, in that the claimed directionality would frustrate the objectives of Sato '577. In particular, Sato '577 unequivocally states at column 4 lines 12-14 that its "nap" is formed by fibrils. The presently claimed rubbing direction, however, disrupts and eliminates the fibrils<sup>2</sup>. As a result, if the rubbing of Sato '577 were along the axial direction now claimed, the fibrils of Sato '577 would be disrupted and eliminated instead of being raised into a nap. As such, Sato '577 actually teaches away from the directionality recited in rejected Claims 21, 31, 32, 34, and 37-41. The rejections thereof based upon Sato '577 should therefore be reversed.

#### Rejection of Claims under 35 U.S.C. §102(b) In View of Sato '577

In addition to Applicants' arguments presented in the Appeal Brief dated May 21, 2007, Applicants respectfully submit that Sato '577 fails to teach or suggest each of the elements of Claims 11, 12, 14-17, 19, 20, 22, and 23 as required under 35 U.S.C. §102(b). In particular, nowhere does Sato '577 teach or suggest lifting nodes from the luminal surface to define a plurality of recesses, but instead specifically teaches away from such a formation.

A commonality among the above-noted rejected claims is that each of such claims recite a method to lift nodes from a surface to define a plurality of recesses. The Examiner alleges that such recesses are formed by the "nap" described in Sato '577. The nap of Sato '577, however, is formed by fibrils<sup>3</sup>. The Examiner asserts that it is inherent that nodes are lifted along with the fibril nap of Sato '577 because PTFE is made up of interconnected nodes and fibrils. However, the present specification at, for example,

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<sup>1</sup> "Transverse" is defined in paragraph 54 and Figure 10 as being substantially parallel to fibril orientation and substantially perpendicular to node orientation.

<sup>2</sup> See, e.g., paragraphs 56 and 42 of the present specification.

<sup>3</sup> See column 4 lines 12-14 of Sato '577.

paragraphs 42 and 49 expressly describe raising nodes to the exclusion of fibrils. Accordingly, it is not inherent, and nowhere does Sato '577 teach or suggest that lifting of a fibril nap necessarily lifts nodes. As such, the claim rejections identified above should be reversed.

Rejection of Claims under 35 U.S.C. §102(b) In View of Dzau et al. '555

Claims 19, 23, 24-30, and 32-34 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dzau et al. '555. As discussed in Applicants' Appeal Brief, it is well understood that for a reference to support a claim rejection under 35 U.S.C. §102, such reference must alone disclose each and every element of the rejected claim. Here, it is clear that Dzau et al. '555 fail to teach or disclose at least the claim element of lifting nodes from the surface, which element is found in each of the claims rejected by Dzau et al. '555. In fact, nowhere do Dzau et al. '555 even suggest a physical change in the prosthesis structure as a result of introduction of frictional force. Consequently, it is impermissible for the Examiner to support a rejection under 35 U.S.C. §102 with the disclosure of Dzau et al. '555.

The Examiner asserts that the force of fluid upon the vascular prostheses in the cell-seeding process of Dzau et al. '555 would inherently cause nodes to be lifted from the prosthesis surface. Nary a hint of such an effect is described in Dzau et al. '555 and it is respectfully submitted that the Examiner is relying upon the disclosure of the present application to infer such inherency. Such reliance, of course, is impermissible in rejecting a claim based upon alleged prior art.

The Examiner erroneously alleges that the lifting of nodes is inherent from the force of introduced fluid in Dzau et al. '555 "since recesses are formed as a result of passing over the surface and the cells adhered and filled them". In actuality, however, the pores into which cells are seeded through the process of Dzau et al. '555 exist prior to the introduction of the seeding fluid<sup>4</sup>. No disclosure is found Dzau et al. '555 that the pore structure of the prostheses undergoes any physical change as a result of the fluid introduction, much less that new recesses are created through such fluid introduction. In

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<sup>4</sup> See, e.g., col. 4 line 55 – col. 5 line 10; and col. 5 lines 57 – 67 of Dzau et al. '555.

view of the above, the above-noted rejection of claims based upon Dzau et al. '555 should be reversed.

**Summary**

For the foregoing reasons, Applicants respectfully submit that the claim rejections are unfounded and unsupported by the cited references, whether taken alone or in combination. Accordingly, the claim rejections should be reversed, and all of the pending claims should be allowed.

Respectfully submitted,

HAUGEN LAW FIRM PLLP

A handwritten signature in dark ink, appearing to read 'Mark J. Burns', is written over the printed name.

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